EUROPEAN COMMISSION

Brussels, 27.7.2011
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COMMISSION IMPLEMENTING DECISION

of 27.7.2011

amending the marketing authorisation for "Faslodex - Fulvestrant", a medicinal product for human use, granted by Decision C(2004)851

(Text with EEA relevance)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1],

Having regard to Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products[2], and in particular Article 17(2) thereof,

Having regard to the application submitted on 24 April 2011 by AstraZeneca UK Limited under Article 16 of Regulation (EC) No 1234/2008,

Having regard to the notification submitted by AstraZeneca UK Limited, under the second subparagraph of Article 14(1) of Regulation (EC) No 1234/2008,

Having regard to the opinion(s) of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 23 June 2011,

Whereas:

(1) The European Medicines Agency has informed the marketing authorisation holder and the Commission of its favourable opinion on the major variation type II and of the need to amend the marketing authorisation for the medicinal product "Faslodex - Fulvestrant" which is entered in the Community Register of Medicinal Products under numbers EU/1/03/269/001-002.

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1 OJ L 136, 30.4.2004, p. 1.

2 OJ L 334, 12.12.2008, p. 7.

(2) The European Medicines Agency has informed the marketing authorisation holder and the Commission of its favourable opinion on a minor variation notified between 8 December 2010 and 23 June 2011.

(3) The marketing authorisation should be updated and Decision C(2004)851 of 10 March 2004 should therefore be amended accordingly. The Community Register of Medicinal Products should also be updated.

(4) For the sake of clarity and transparency, it is advisable, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C(2004)851 should therefore be replaced,

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2004)851 is amended as follows:

1) The following notification for a minor variation is added to the marketing authorisation:

Application number	Scope (EU numbers affected)
EMEA/H/C/540/IG/35	C.I.9.i) (EU/1/03/269/001-002)

2) Annex I is replaced by the text set out in Annex I to this Decision;

3) Annex II is replaced by the text set out in Annex II to this Decision;

4) Annex III B is replaced by the text set out in Annex III B to this Decision.

Article 2

This Decision is addressed to AstraZeneca UK Limited, Alderley Park, Macclesfield, Cheshire, SK10 4TG United Kingdom.

Done at Brussels, on 27.7.2011.

For the Commission
Paola TESTORI COGGI
Director-General